Minutes

Advisory Committee on Novel Foods and Process. Minutes of the 170th Meeting held on the 5th and 6th of February 2025

These minutes are subject to confirmation by the Committee.

Members are required to declare any personal interest in matters under discussion. Where Members have a particularly close association with any item, the Chairman will limit their involvement in the discussion. In cases where an item is to be discussed in their absence, a member may make a statement before leaving.

Minutes of the 170th meeting of the Advisory Committee on Novel Foods and Processes, held on the 5th and 6th of February as a hybrid meeting**.**

Attendance

Committee Chair

Dr Camilla Alexander-White

Committee Members

Dr Anton Alldrick

Ms Alison Austin

Professor George Bassel

Dr Mark Berry

Dr Meera Cush

Dr Cathrina Edwards

Professor Paul Fraser

Dr Sophie Foley

Dr Andy Greenfield

Professor Wendy Harwood

Professor Huw D. Jones

Dr Ray Kemp

Dr Elizabeth Lund

Dr Lynn McIntyre

Professor Clare Mills

Dr Isabel Skypala

Professor Susan Fairweather-Tait

Prof Hans Verhagen

Dr Maureen Wakefield

Dr Lesley Stanley - Co-opted Member–CBD subgroup

Apologies

Professor Dimitris Charalampopoulos

Professor Bruce Whitelaw

Assessor

Mr Paul Tossell - Head of Radiological, GM, Novel Foods & Radiological Protection

Observers FSA

Professor Rick Mumford - Head of Science, Evidence and Research

Mr Chris Rundle - Head of Regulated Products Risk Assessment

Ms Melanie Harries - Head of Cell-Cultivated Products (Policy Strategy)

Mr Joshua Ravenhill - Head of Policies Priorities

Mr Adekunle Adeola - Senior Policy Adviser

Mr Shaun Jacobs - Senior Policy Advisor

Ms Sophie Burder - Policy Advisor

Dr Eleanor McCartney - Senior Policy Adviser

Ms Barbora Peck - Policy Adviser

Ms Beth Sung - Senior Policy Adviser

Observers Devolved administration

Ms Kaila Lee - Policy, FSA Wales

Mr Peter Madden - Policy, FSA Wales

Mr Jeremy Mills - Policy, FSA Wales

Dr Karen Pearson - Food Standards Scotland

Ms Krystle Boss - Food Standards Scotland

Mr Daniel Lynch - Policy, FSA NI

Observers (External)

Mr Peter Gregory - Science Council

Ms Ivy Wellman - Defra

Observers for open session (External)

Mr Seth Roberts - Good Food Institute Europe

Mr Maxwell Shaughnessy - Cellular Agriculture Ltd

Mr Joe Taylor - Hoxton Farms

Mr Daniele Leonarduzzi - RSSL

Ms Lisa Ceroni - Mosa Meat

Mr Wayne Bonadie - Uncommon Bio Limited

Claude Rescan - Vital Meat

Mr Ernst Van Orsouw - Roslin Technologies

Kel Potts - Split Foods

Dr Eirini Theodosiou - Aston University

Ms Naya McCartney - Vow

Ms Ruth Wonfor - Aberystwyth University

Mr Ben Kinder - Ivy Farm Technologies

Mr Josi Buerger - Nutreco

Mr Nigel Baldwin - Baldwin Advisory Services Ltd

Ms Helder Cruz - Meatly

Ms Yuki Hanyu - IntegriCulture Inc.

Ms Fiona Carter - University of Bath

Chinmayi Nadiger - Umami Bioworks Pte Ltd

Ms Prithvi Kodialbail - Extracellular

Ms Petra Hanga - University College London

Ms Bianca Le - Mission Barns

Ms Hannah Lester - Atova Regulatory Consulting SLU

Secretariat

Mrs Ruth Willis - Technical Secretary ACNFP

Dr Rachael Oakenfull - Technical Secretary PGT

Ms Priscilla Wanjiru - Lead Secretariat

Dr Karin Heurlier - PGT Lead Secretariat

Mr Ben Haynes - Science Secretariat

Dr Daniel Lloyd - Science Secretariat

Miss Jenny Rees - Science Secretariat

Mr Matt Hall - Science Secretariat

Mrs Afielia Choudhry - Science Secretariat

Dr Annalisa Leone - Science Secretariat

Ms Lucy Thursfield - Science Secretariat

Mr Will Smith - Science Secretariat

Miss Victoria Balch - Administrative Secretariat

Mrs Carol Scott - Administrative Secretariat

1. Apologies and Announcements

Apologies were received from Professor Bruce Whitelaw and Professor Dimitris Charalampopulos for non-attendance on both days, while Dr Mark Berry and Dr Isabel Skypala could not attend on day 2.

The Chair reminded Members of the need to announce any potential conflicts of interests prior to the discussions on each item.

Dr Anton Alldrick previously declared conflict of interest in relation to CBD. Professor Hans Verhagen declared conflicts of interest in relation to Fermotein and Solein. The Chair and Secretariat advised that these members would not be present for the discussions on these items.

The members were also informed of Dr Daniel Lloyd’s promotion to lead the work on Cell Cultivated Proteins. They wished him well in his new role.

2. Welcome

Chair welcomed the Members, representatives from the FSA, the observers from the devolved administrations and the Secretariat team.

3. Meeting Minutes for the 169th Meeting

ACNFP/169/MINS

The Committee agreed the 169th meeting draft minutes subject to minor amendments for publication on the ACNFP website.

4. Matters Arising from the last meeting

ACNFP/169/MA

The Secretariat reported on actions from the 169th meeting:

- Mung Bean Protein RP32 – The Committee Advice Document for this application was reviewed by the members with a few amendments suggested. A revised version will be circulated to members for final comment in the next few weeks.
- Allulose RP1130 – The Committee reviewed this application for the first time. Following the ACNFP's advice, further information from the applicant was sought to support the ongoing assessment in relation to identity, production process, composition, specification, ADME and allergenicity.
- Alternative and Cell Cultivated Proteins – Following the review by members of the Committee on the scope and terms of reference for the new Subgroup, an open session will be held as item 07 to support the beginning of this 2-year work programme.
- Cannabidiol RP354 – Following review of this new application, the Secretariat sought further information from the applicant to address questions on the production process. This response will be shared with selected members when available and the final text cleared by Chair's action.
- Cannabidiol RP521 – Following review of this new application, the Secretariat sought further information from the applicant on the compositional data. This was provided and the updated Committee Advice Document was agreed by Chair's action.
- DMB RP1351 (ACNFP/170/01) and Krill RP1290 (ACNFP/170/01) – These intersessional items 5 and 6 have been finalised following consultation with members and are now going through the publication process.
- It was noted that items 5 and 6 were intersessional papers on Dried Miracle Berry and Krill protein that were reported as part of matters arising above.

7. THC Statement (reserved business)

ACNFP/170/03

The Committee reviewed a draft statement on delta-9-tetrahydrocannabinol (Δ^9-THC) as a contaminant of hemp-derived food. Discussion was held around the terminology used to describe the identified safe level of the contaminant and it was advised that the basis for the terminology should be very clear. The Committee also advised that the data used to inform the position and which contaminants the position refers to needs to be accurately and clearly described. Slight amendments to the text were agreed that addressed these points to make it more understandable by non - experts.

Additional comments were made regarding specific wording throughout the document and after this review the Committee agreed to accept the statement for use in the risk assessment of future CBD products and other hemp-derived foods.

Action: Adopt statement subject to minor amendments.

8. CBD RP340 (reserved business)

ACNFP/170/04

The Committee reviewed an application and a draft Committee Advice Document for highly purified isolated CBD for the second time. Additional data provided by the applicant, on the genotoxicity of the novel food, was reviewed. Members of the Committee agreed that the additional information provided was of suitable quality for risk assessment and appropriately evidenced that the novel food was not genotoxic.

The Committee noted that there was a discrepancy between the solvent specifications and the data presented within the compositional analysis of the novel food. Further information is to be sought from the applicant regarding the solvent residues in the composition of the novel food. Members of the ACNFP agreed to finalise the Committee Advice Document subject to minor amendments and the response from the applicant.

Action: Secretariat to request for further information from applicant regarding solvent residues in the novel food.

Action: Committee Advice document to be updated for clearance by Chair’s action.

9. CBD RP176 (reserved business)

ACNFP/170/05

The Committee discussed a group A CBD application applying for 97.5% purity CBD isolate which provided specification results of >98% purity CBD.

Members queried whether the specification matched the data supplied to support the safety of the novel food. While no safety concern was expected from the spec of 97.5 based on the analytical composition of the novel food, the data submitted supported a higher specification of CBD for the product. They recommended this be discussed with the applicant.

A number of CBD CAD template updates were suggested for consistency.

Action: Secretariat to discuss the specification with the applicant.

Action: Secretariat to amend Committee Advice Document in light of Committee feedback for clearance by Chair's action.

10. CBD RP294 (reserved business)

ACNFP/170/06

The Committee discussed a group A CBD application applying for 97% purity CBD isolate which provided specification results of >98% purity CBD.

Members queried whether the specification matched the data supplied to support the safety of the novel food. While no safety concern was expected from the spec of 97 based on the analytical composition of the novel food, the data submitted supported a higher specification of CBD for the product. They recommended this be discussed with the applicant.

Members noted the absence of residual solvent and mycotoxin results from the specification. It was noted that these had been reviewed and were acceptable but would benefit from inclusion in the specification to support the management of these parameters in production. It was recommended that the applicant should be requested to update the specification with these parameters.

A number of CBD CAD template updates were suggested for consistency.

Action: Secretariat to discuss the specification with the applicant.

Action: Secretariat to amend Committee Advice Document in light of Committee feedback for clearance by Chair's action.

11. Open session on Cell Cultivated Products

ACNFP/170/07

The Committee discussed the key hazards, and their associated uncertainties, that will impact the assessment of safety for cell cultivated products. Members were invited to use this discussion not to address any specific hazards, but to identify key questions to be considered by the FSA CCP sandbox and ACNFP CCP Subgroup. To limit the scope of these hazards, the discussion was limited to animal tissue cells grown in cell culture specifically.

A constructive discussion session then occurred which was observed by 25 external observers to provide increased transparency to the working of the ACNFP . Observers and Committee members provided their views on the relative impact of these hazards on the safety of the final product. A range of questions surfaced as part of the discussion that will inform the workplan for the CCP subgroup for the next two years.

Action: Secretariat to reflect the discussion in a report on the open session for publication

Action: Secretariat to send separate feedback forms to Committee members and observers to rank the importance of hazards and identify relevant expertise to support the work of the sandbox.

12. Items for Information

12.1 Novel Food Policy Update - Written

The Committee was provided with a written update on the issues under consideration regarding novel foods.

12.2 GM Policy Update - Written

The Committee was provided with an written update on the issues under consideration regarding GM.

12.3 SACS Update - Written

The Committee was provided with a written update on the activities of the different SACs.

12.4 Decision Panel’s Outcome Update - Written

The Committee was provided with a written update on the outcomes of the FSA‘s Regulated Products Decision Panel.

13. Fermotein RP1215

ACNFP/170/08

An application for *Rhizomucor pusillus* biomass (Fermotein®) a protein and fibre ingredient for use in the general population was reviewed for the first time. The discussion identified areas that required further information from the applicant to complete the assessment.

Members commented that the genome sequence provided was not complete and the implications for the robustness of the bioinformatics analysis should be explored further. This would impact the safety conclusions that could be drawn on virulence, antibiotic synthesis, mycotoxins etc., and allergenicity of the source organism.

Members agreed that the production process needed better description particularly in relation to the management of microbial contamination and drying of the novel food. Questions were also raised on the management of the microorganism so that its characteristics, and identity were consistent over time.

Gaps in the compositional analysis were identified. It was recommended that when calculating the protein content, the calculated nitrogen conversion factor based on the amino acid composition that had been identified from their wider testing should be used, rather than the default factor of 6.25. This was to allow a better understanding of the potential for nutritional disadvantage as opposed to the figures required for the nutrition declaration. The data on the RNA content of the novel food was noted with queries raised as to how this related to potential impacts on human health, specifically in relation to uric acid production.

Members also noted there was variability between the data provided for the compositional analysis and that provided as specification. It was recommended that further information be sought on the sources of variability to ensure that the specification values accurately reflected the characteristics of the novel food as produced.

Based on the evidence provided for protein quality, the Committee recommended the applicant clarify how they have ensured that use of the novel food to replace

high quality protein sources would not be nutritionally disadvantageous to infants (0- 12 months), young children (1-3 years), elderly (65-75 years) and very elderly (75+).

Members queried whether the potential impact of additional nitrogen in the colon both from a toxicity and impact on the microbiome perspective had been considered. This, along with data gaps from the toxicology information would benefit from further review.

Action: The Secretariat to seek further information from the applicant to further the assessment of the novel food.

14. Solein RP1326

ACNFP/170/09

An application for *Xanthobacter* sp. SoF1 cells (Solein®) a protein ingredient for use by the general population was reviewed for the first time. The discussion of the application identified areas where further information is required to complete the assessment.

Members noted that the *Xanthobacter* sp. SoF1 is considered to be a new species based on the bioinformatics data provided. The Committee sought further clarification on the genus/species classification and completeness of the genome that had been used in the bioinformatic analysis to ensure that evaluation of safety was suitably robust. Additional information relating to the phenotype of *Xanthobacter* sp. SoF1 was also requested.

Members reviewed the details of the novel food production process. Further information regarding the management of the master cell bank, and the cell cultivation process, was required. Further detail on certain points in the food safety management plan were also required.

The Committee noted variations in the carbohydrate and moisture content for novel food batches manufactured at different time points. Clarification was needed to explain this variability. Further analysis of the dietary fibre fraction was also suggested in order to characterise the novel food appropriately. It was recommended that when calculating the protein content, the calculated conversion factor based on the amino acid composition be used, rather than the default factor of 6.25.

Members noted the specification levels for the nutrient parameters were broad and they requested information on the sources of variation and how the compositional analysis had informed the specification values. The Committee also requested that nucleobases and water activity be added to the specification so that these parameters would be controlled in production.

The food categories proposed by the applicant include products consisting of 100% of the novel food. Members sought clarification on these proposed uses as well as how nutritional disadvantage for the young and the elderly would be avoided if major food groups containing high quality proteins were being replaced. Further information was also sought on the impact for consumers who use analogues products such as meat or dairy substitutes containing the novel food as a replacement food in their diet.

The Committee also reviewed the anticipated exposure levels of iron and manganese from consumption of the novel food. The applicant was requested to consider the impact of these minerals in different population groups and consider mitigation steps where appropriate.

Action: The Secretariat to seek further information from the applicant to further the assessment of the novel food.

15. MS11 × RF3 × MON 88302 Brassica Napus (Oilseed Rape), RP2029 (reserved business)

ACNFP/170/10

An application for the authorisation of genetically modified oilseed rape MS11 x RF3 x MON 88302 was reviewed and collectively endorsed by the full ACNFP Committee.

Action: Secretariat to update Committee Advice document in light of comments before finalising.

16. Bt11 × MIR162 × MIR604 × MON 89034 × 5307 × GA21 Maize RP2044 (reserved business)

ACNFP/170/11

An application for the authorisation of genetically modified maize Bt11 × MIR162 × MIR604 × MON 89034 × 5307 × GA21 was reviewed and collectively endorsed by the full ACNFP Committee.

Action: Secretariat to update Committee Advice document in light of comments before finalising.

17. EPA+DHA Brassica Napus L. (Oilseed Rape), RP2065 (reserved business)

ACNFP/170/12

An application for the authorisation of genetically modified oilseed rape EPA+DHA, was reviewed and collectively endorsed by the full ACNFP Committee.

Action: Secretariat to Secretariat to update Committee Advice document in light of comments before finalising.

Date of next meeting

The next ACNFP meeting will be held online on 24th April 2025.